

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of Sharon A. Baughman et al. Serial No.: To Be Assigned Filed: June 20, 2003 For: Dosages for Treatment with Anti-ErbB2 Antibodies	Group Art Unit: To Be Assigned Examiner: To Be Assigned Express Mail No. EV 351 923 988 US June 20, 2003 Wendy M. Lee
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INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants submit herewith patents, publications or other information (attached hereto and listed on the attached revised Form PTO-1449) of which they are aware, which they believe may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 CFR §1.56.

This Information Disclosure Statement is filed in accordance with the provisions of:

37 CFR §1.97(b)

- within three months of the filing date of the application other than a continued prosecution application under 37 CFR §1.53(d); **or**
- within three months of the date of entry of the national stage of a PCT application as set forth in 37 CFR§1.491, **or**
- before the mailing of the first Office action on the merits; **or**
- before the mailing of the first Office action after the filing of a request for a continued examination under 37 CFR §1.114.

37 CFR §1.97(c)

- by the applicant after the period specified in 37 CFR §1.97(b), but prior to the mailing date of any of a final action under 37 CFR §1.113, or a notice of allowance under 37 CFR §1.311, or an action that otherwise closes prosecution in the application, and is accompanied by either the fee set forth in 37 CFR §1.17(p) **or** a statement as specified in 37 CFR §1.97(e), as checked below.

37 CFR §1.97(d)

- after the period specified in CFR §1.97(c), and is accompanied by the fee set forth in 37 CFR §1.17(p) **and** a statement as specified in 37 CFR §1.97(e), as checked below.

[If either of boxes 37 CFR §1.97(c) or 37 CFR §1.97(d) is checked above, the following statement under 37 CFR §1.97(e) may need to be completed.]

- 37 CFR §1.97(e)** Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement.
- 37 CFR §1.704(d)** Each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and the communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of this information disclosure statement. Therefore, in accordance with the provisions of 37 CFR §1.704(d), the filing of this information disclosure statement will not be considered a failure to engage in reasonable efforts to conclude prosecution under 37 CFR §1.704.
- The U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 07-0630 in the amount of \$180.00 to cover the cost of this Information Disclosure Statement under 37 CFR §1.17(p). Any deficiency or overpayment should be charged or credited to this deposit account.

A list of the patent(s) or publication(s) is set forth on the attached revised Form PTO-1449 (Modified). A copy of the items on PTO-1449 is supplied herewith.

Those patent(s) or publication(s) which are marked with an asterisk (*) in the attached PTO-1449 form are not supplied because they were previously cited by or submitted to the Office in a prior application Serial No. 09/648,067, filed August 25, 2000 and relied upon in this application for an earlier filing date under 35 USC §120.

BLAST results enclosed:

The undersigned also wishes to bring to the attention of the Examiner BLAST results of computerized alignments of the against sequences contained in the nucleotide and protein databases. The BLAST results are provided in paper form and are identified as reference "BLAST Results A-1 - A-()" (nucleotide) and "BLAST Results B-1 - B-()" (protein) on the PTO Form 1449. Applicant requests that these references also be considered and that the Form 1449 be initialed to indicate the Examiner's consideration of the references.

A concise explanation of relevance of the items listed on PTO-1449 is:

- [X] not given
- [] given for each listed item
- [] given for only non-English language listed item(s) [Required]
- [] in the form of an English language copy of a Search Report from a foreign patent office, issued in a counterpart application, which refers to the relevant portions of the references.

In accordance with 37 CFR §1.97(g), the filing of this information disclosure statement shall not be construed as a representation that a search has been made.

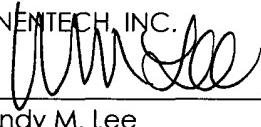
In accordance with 37 CFR §1.97(h), the filing of this information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in 37 CFR § 1.56(b).

The Commissioner is hereby authorized to charge any additional fees required under 37 CFR 1.16 and 1.17 for this Information Disclosure Statement, or credit overpayment to Deposit Account No. 07-0630. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

GENENTECH, INC.

By:


Wendy M. Lee
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Date: June 20, 2003



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PATENT TRADEMARK OFFICE

FORM PTO-1449				U.S. Dept. of Commerce Patent and Trademark Office	Atty Docket No. P1775R1D1	Serial No. To Be Assigned
LIST OF DISCLOSURES CITED BY APPLICANT (Use several sheets if necessary)				Applicant Baughman et al.		
				Filing Date 20 Jun 2003	Group To Be Assigned	

U.S. PATENT DOCUMENTS

Examiner Initials		Document Number	Date	Name	Class	Subclass	Filing Date
*	1	4,676,980	30.06.87	Segal et al.			
*	2	4,753,894	28.06.88	Frankel et al.			
*	3	4,816,567	28.03.89	Cabilly et al.			
*	4	4,935,341	19.06.90	Bargmann et al.			
*	5	4,943,533	24.07.90	Mendelsohn et al.			
*	6	4,968,603	06.11.90	Slamon et al.			
*	7	4,975,278	04.12.90	Senter et al.			
*	8	5,169,774	08.12.92	Frankel et al.			
*	9	5,183,884	02.02.93	Kraus et al.			
*	10	5,288,477	22.02.94	Bacus, S.			
*	11	5,359,046	25.10.94	Capon et al.			
*	12	5,367,060	22.11.94	Vandlen et al.			
*	13	5,401,638	28.03.95	Carney et al.			
*	14	5,464,751	07.11.95	Greene et al.			
*	15	5,480,968	02.01.96	Kraus et al.			
*	16	5,578,482	26.11.96	Lippman et al.			
*	17	5,604,107	18.02.97	Carney et al.			
*	18	5,641,869	24.06.97	Vandlen et al.			
*	19	5,663,144	02.09.97	Greene et al.			
*	20	5,677,171	14.10.97	Hudziak et al.			
*	21	5,705,157	06.01.98	Greene, M. L.			
*	22	5,720,937	24.02.98	Hudziak et al.			
*	23	5,720,954	24.02.98	Hudziak et al.			
*	24	5,725,856	10.03.98	Hudziak et al.			
*	25	5,726,023	10.03.98	Cheever et al.			
*	26	5,728,687	17.03.98	Bissery, M.			
*	27	5,747,261	05.05.98	King et al.			
*	28	5,770,195	23.06.98	Hudziak et al.			
*	29	5,772,997	30.06.98	Hudziak et al.			
*	30	5,776,427	07.07.98	Thorpe et al.			
*	31	5,783,186	21.07.98	Arakawa et al.			
*	32	5,801,005	01.09.98	Cheever et al.			
*	33	5,821,337	13.10.98	Carter et al.			
*	34	5,824,311	20.10.98	Greene et al.			
*	35	5,834,229	10.11.98	Vandlen et al.			
*	36	5,837,243	17.11.98	Deo et al.			

Examiner	Date Considered
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Examiner Initials		Document Number	Date	Name	Class	Subclass	Filing Date
	* 37	5,837,523	17.11.98	Greene et al.			
	* 38	5,840,525	24.11.98	Vandlen et al.			
	* 39	5,846,538	08.12.98	Cheever et al.			
	* 40	5,856,110	05.01.99	Vandlen et al.			
	* 41	5,859,206	12.01.99	Vandlen et al.			
	* 42	5,869,445	09.02.99	Cheever et al.			
	* 43	5,876,712	02.03.99	Cheever et al.			
	* 44	5,877,305	02.03.99	Huston et al.			
	* 45	5,908,835	01.06.99	Bissery, M.			
	* 46	5,910,486	08.06.99	Curiel et al.			
	* 47	5,922,845	13.07.99	Deo et al.			
	* 48	5,939,531	17.08.99	Wels et al.			
	* 49	5,968,511	19.10.99	Akita et al.			
	* 50	5,977,322	02.11.99	Marks et al.			
	* 51	5,985,553	16.11.99	King et al.			
	* 52	6,015,567	18.01.00	Hudziak et al.			
	* 53	6,028,059	22.02.00	Curiel et al.			
	* 54	6,054,297	25.04.00	Carter et al.			
	* 55	6,054,561	25.04.00	Ring, D. B.			
	* 56	6,096,873	01.08.00	Schaefer et al.			
	* 57	6,123,939	26.09.00	Shawver et al.			
	* 58	6,165,464	26.12.00	Hudziak et al.			
	* 59	6,333,348	25.12.01	Vogel et al.			

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Examiner Initials		Document Number	Date	Country	Class	Subclass	Translation Yes	No
	* 60	0,003,089 A1	25.07.79	EPO (ENGLISH ABSTRACT ATTACHED)				
	* 61	0,599,274 A1	01.06.94	EPO				
	* 62	616,812 A1	28.09.94	EPO				
	* 63	711,565	26.08.98	EPO				
	* 64	2,761,543B2	04.06.98	JAPAN (TRANSLATION ATTACHED)				
	* 65	2,895,105B2	24.05.99	JAPAN (ENGLISH ABSTRACT AND CLAIMS)				
	* 66	3-240498	25.10.91	JAPAN (ENGLISH ABSTRACT ATTACHED)				
	* 67	5-117165	14.05.93	JAPAN (ENGLISH ABSTRACT ATTACHED)				
	* 68	5-170667	09.07.93	JAPAN (ENGLISH ABSTRACT ATTACHED)				
	* 69	5-213775	24.08.93	JAPAN (ENGLISH ABSTRACT ATTACHED)				

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FOREIGN PATENT DOCUMENTS							
Examiner Initials		Document Number	Date	Country	Class	Subclass	Translation Yes No
		* 70 5-317084	03.12.93	JAPAN (ENGLISH ABSTRACT ATTACHED)			
		* 71 7-59588	07.03.95	JAPAN (ENGLISH ABSTRACT ATTACHED)			
		* 72 95,006,982B2	30.01.95	JAPAN (ENGLISH ABSTRACT AND CLAIMS)			
		* 73 WO 00/61185	19.10.00	PCT			
		* 74 WO 89/06692	27.07.89	PCT			
		* 75 WO 90/14357	29.11.90	PCT			
		* 76 WO 91/00360	10.01.91	PCT			
		* 77 WO 92/10573	25.06.92	PCT			
		* 78 WO 92/20373	26.11.92	PCT			
		* 79 WO 92/20798	26.11.92	PCT			
		* 80 WO 93/12220	24.06.93	PCT			
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		* 83 WO 94/00136	06.01.94	PCT			
		* 84 WO 94/04690	03.03.94	PCT			
		* 85 WO 94/22478	13.10.94	PCT			
		* 86 WO 94/28127	08.12.94	PCT			
		* 87 WO 95/16051	15.06.95	PCT			
		* 88 WO 95/17507	29.06.95	PCT			
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		* 91 WO 96/27011	06.09.96	PCT			
		* 92 WO 97/04801	13.02.97	PCT			
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		* 94 WO 97/27848	07.08.97	PCT			
		* 95 WO 97/35885	02.10.97	PCT			
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*102	Arteaga et al., "p185c-erbB-2 Signaling Enhances Cisplatin-induced Cytotoxicity in Human Breast Carcinoma Cells: Association Between an Oncogenic Receptor Tyrosine Kinase and Drug-induced DNA Repair" <i>Cancer Research</i> 54(14) :3758-3765 (Jul 15, 1994)						
*103	Bacus et al., "Differentiation of Cultured Human Breast Cancer Cells (AU-565 and MCF-7) Associated With Loss of Cell Surface HER-2/neu Antigen" <i>Molecular Carcinogenesis</i> 3(6) :350-362 (1990)						
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OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)				
*104	Bacus et al., "Tumor-inhibitory Monoclonal Antibodies to the HER-2/Neu Receptor Induce Differentiation of Human Breast Cancer Cells" <u>Cancer Research</u> 52(9):2580-2589 (May 1, 1992)			
*105	Baselga and Mendelsohn, "Receptor Blockade With Monoclonal Antibodies As Anti-Cancer Therapy" <u>Pharmac Ther.</u> 64:127-154 (1994)			
*106	Baselga et al., "Anti HER2 Humanized Monoclonal Antibody (MAb) Alone and in Combination with Chemotherapy Against Human Breast Carcinoma Xenografts" <u>Proceedings of ASCO-13th Annual Meeting</u> (Abstract #53), Dallas, TX 13:63 (Mar 1994)			
*107	Baselga et al., "HER2 Overexpression and Paclitaxel Sensitivity in Breast Cancer: Therapeutic Implications" <u>Oncology</u> (Supplement No. 2) 11(3):43-48 (March 1997)			
*108	Baselga et al., "Monoclonal Antibodies Directed Against Growth Factor Receptors Enhance the Efficacy of Chemotherapeutic Agents." <u>Annals of Oncology</u> (abstract #010) 5(Suppl. 5) (1994)			
*109	Baselga et al., "Phase II Study of Weekly Intravenous Recombinant Humanized Anti-p185HER2 Monoclonal Antibody in Patients With HER2/neu-Overexpressing Metastatic Breast Cancer" <u>J. Clin. Oncol.</u> 14(3):737-744 (Mar 1996)			
*110	Baselga et al., "Recombinant Humanized Anti-HER2 Antibody (Herceptin) Enhances the Antitumor Activity of Paclitaxel and Doxorubicin against HER2/neu Overexpressing Human Breast Cancer Xenografts" <u>Cancer Research</u> 58:2825-2831 (July 1998)			
*111	Carbonell Castellon et al., "Efficacy and safety of 3-weekly Herceptin (H) monotherapy in women with HER2-positive metastatic breast cancer (MBC): preliminary data from a phase II study" <u>Proc Am Soc Clin Oncol</u> (Abstract #73 from the 2002 ASCO Meeting) 21:19a (2002)			
*112	Carbonell et al., "Efficacy and safety of 3-weekly Herceptin monotherapy in women with HER2-positive metastatic breast cancer: preliminary data from a phase II study" (Oral presentation at the 38th Annual Meeting of the American Society of Clinical Oncology, May 18-21, 2002 in Orlando, Florida)			
*113	Carter et al., "Humanization of an Anti-p185HER2 Antibody For Human Cancer Therapy" <u>Proc. Natl. Acad. Sci. USA</u> 89:4285-4289 (May 1992)			
*114	Chothia and Lesk, "Canonical Structures for the Hypervariable Regions of Immunoglobulins" <u>J. Mol. Biol</u> 196:901-917 (1987)			
*115	Cobleigh et al., "Multinational study of the efficacy and safety of humanized anti-HER2 monoclonal antibody in women who have HER2-overexpressing metastatic breast cancer that has progressed after chemotherapy for metastatic disease" <u>Journal of Clinical Oncology</u> 17(9):2639-2648 (Sep 1999)			
*116	D'Souza and Taylor-Papadimitriou., "Overexpression of ERBB2 in Human Mammary Epithelial Cells Signals Inhibition of Transcription of the E-Cadherin Gene." <u>Proc. Natl. Acad. Sci. USA</u> 91(15):7202-7206 (Jul 19, 1994)			
*117	De Santis et al., "Radiolabeled Antibody Targeting of the HER-2/neu Oncoprotein" <u>Cancer Research</u> 52:1916-1923 (1992)			
*118	Di Fiore et al., "erbB-2 Is A Potent Oncogene When Overexpressed In NIH/3T3 Cells." <u>Science</u> 237(4811):178-182 (Jul 10, 1987)			
*119	Drebin et al., "Down-Modulation of an Oncogene Protein Product and Reversion of the Transformed Phenotype by Monoclonal Antibodies" <u>Cell</u> 41(3):695-706 (Jul 1985)			
*120	Drebin et al., "Inhibition of Tumor Growth By a Monoclonal Antibody Reactive With an Oncogene-Encoded Tumor Antigen" <u>Proc. Natl. Acad. Sci.</u> 83:9129-9133 (1986)			
*121	Drebin et al., "Monoclonal Antibodies Reactive With Distinct Domains of the neu Oncogene-Encoded p185 Molecule Exert Synergistic Anti-Tumor Effects In Vivo" <u>Oncogene</u> 2:273-277 (1988)			
*122	Drebin et al., "Monoclonal Antibodies Specific for the neu Oncogene Product Directly Mediate Anti-tumor Effects In Vivo" <u>Oncogene</u> 2(4):387-394 (1988)			
*123	Fendly, B.M. et al., "Characterization of Murine Monoclonal Antibodies Reactive to Either the Human Epidermal Growth Factor Receptor or HER2/neu Gene Product" <u>Cancer Research</u> 50:1550-1558 (Mar 1, 1990)			
Examiner		Date Considered		
<p>*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>				

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OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)					
*124	Fleiss, JL <u>Statistical Methods for Rates and Proportions</u> , 2nd edition, New York, NY:Wiley pps. 13-17 (1981)				
*125	Gelmon et al., "Pharmacokinetics and safety of Herceptin when administered every 3 weeks to women with metastatic breast cancer" (Oral presentation at the 37th Annual Meeting of the American Society of Clinical Oncology, May 12-15, 2001 in San Francisco, CA)				
*126	Gemzar (gemcitabine HCL), "Product Information - PDR" (2000)				
*127	Goldenberg, M., "Trastuzumab, a Recombinant DNA-Derived Humanized Monoclonal Antibody, a Novel Agent for the Treatment of Metastatic Breast Cancer" <u>Clinical Therapeutics</u> 21(2):309-318 (1999)				
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*129	Guy et al., "Expression of the neu Protooncogene in the Mammary Epithelium of Transgenic Mice Induces Metastatic Disease." <u>Proc. Natl. Acad. Sci. USA</u> 89(22):10578-10582 (Nov 15, 1992)				
*130	Hancock et al., "A Monoclonal Antibody Against the c-erbB-2 Protein Enhances the Cytotoxicity of cis-Diamminedichloroplatinum Against Human Breast and Ovarian Tumor Cell Lines" <u>Cancer Research</u> 51:4575-4580 (Sep 1, 1991)				
*131	Harris et al., "A population pharmacokinetic (PK) model for Herceptin (H) and implications for clinical dosing" (Oral presentation at the 38th Annual Meeting of the American Society of Clinical Oncology, May 18-21, 2002 in Orlando, Florida)				
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*133	Harwerth et al., "Monoclonal Antibodies Against the Extracellular Domain of the erbB-2 Receptor Function as Partial Ligand Agonists" <u>Journal of Biological Chemistry</u> 267(21):15160-15167 (Jul 25, 1992)				
*134	Hudziak et al., "Increased Expression of the Putative Growth Factor Receptor p185HER2 Causes Transformation and Tumorigenesis of NIH 3T3 Cells." <u>Proc. Natl. Acad. Sci. USA</u> 84(20):7159-7163 (Oct 1987)				
*135	Hudziak et al., "p185HER2 Monoclonal Antibody Has Antiproliferative Effects In Vitro and Sensitizes Human Breast Tumor Cells to Tumor Necrosis Factor" <u>Molecular & Cellular Biology</u> 9(3):1165-1172 (Mar 1989)				
*136	Hynes and Stern., "The Biology of erbB-2/neu/HER-2 and Its Role in Cancer." <u>Biochimica et Biophysica Acta</u> 1198(2-3):165-184 (Dec 30, 1994)				
*137	Ilgen et al., "Characterization of anti-HER/2 antibodies which inhibit the growth of breast tumor cells in vitro" <u>Proceedings of the American Association for Cancer Research</u> (abstract #3209) 37:470 (Mar 1996)				
*138	Jones et al., "Replacing the Complementarity-Determining Regions in a Human Antibody with Those From a Mouse." <u>Nature</u> . 321:522-525 (May 29, 1986)				
*139	Kasprzyk et al., "Therapy of an Animal Model of Human Gastric Cancer Using a Combination of Anti-erbB-2 Monoclonal Antibodies" <u>Cancer Research</u> 52(10):2771-2776 (May 15, 1992)				
*140	Kotts et al., "Differential Growth Inhibition of Human Carcinoma Cells Exposed to Monoclonal Antibodies Directed against the Extracellular Domain of the HER2/ERBB2 Protooncogene" <u>In Vitro</u> (Abstract #176) 26(3):59A (1990)				
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*142	Lewis et al., "Differential Responses of Human Tumor Cell Lines to Anti-p185HER2 Monoclonal Antibodies." <u>Cancer Immunol. Immunother.</u> 37:255-263 (1993)				
*143	Lewis et al., "Growth Regulation of Human Breast and Ovarian Tumor Cells by Heregulin: Evidence for the Requirement of ErbB2 as a Critical Component in Mediating Heregulin Responsiveness" <u>Cancer Research</u> 56:1457-1465 (Mar 15, 1996)				
Examiner			Date Considered		
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*144	Leyland-Jones et al., "Pharmacokinetics of Herceptin administered with paclitaxel every three weeks" <u>Breast Cancer Res Treat</u> (abstract only) 64:124 (2000)				
*145	Maier et al., "Requirements for the Internalization of a Murine Monoclonal Antibody Directed against the HER-2/neu Gene Product c-erbB-2" <u>Cancer Research</u> 51(19):5361-5369 (Oct 1, 1991)				
*146	Masui et al., "Growth Inhibition of Human Tumor Cells in Athymic Mice by Anti-Epidermal Growth Factor Receptor Monoclonal Antibodies" <u>Cancer Research</u> 44(3):1002-1007 (Mar 1984)				
*147	Masuko et al., "A murine Monoclonal Antibody That Recognizes an Extracellular Domain of the Human c-erbB-2 Protooncogene Product" <u>Jpn J. Cancer Res.</u> 80:10-14 (January 1989)				
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